DEPARTMENT OF HEALTH AND HUMAN SERVICES

95174d

Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2445

Telephone: 949-608-2900
FAX: 949-608-4415

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 15, 2004 W/L 04-05

Elvis U. Saetang, President
Roxy Trading, Inc.
1388 W. Foothill Blvd.
Azusa, CA 91702

Dear Mr. Saetang:

On August 05-17, 2004 , this agency inspected your fish processing facility located at the above address and found serious deviations from the Seafood HACCP regulation (Title 21, Code of Federal Regulations, Part 123 (21 CFR 123)). These include continuing importer verification deviations (Section 123.12 (a)(2)) previously brought to your attention during an inspection conducted at your firm on February 6 and 11, 2004. In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Accordingly, products that your firm processes (including repacking and storage), e.g., dried anchovies and vacuum-packaged, salted mackerel, are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You can find the Act and the Seafood HACCP regulation through the links in FDA's home page at www.fda.gov.

The deviations are as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a), and (b). However your firm does not have a HACCP plan for vacuum-packaged, salted mackerel to include control of the food safety hazards of *Clostridium botulinum* and histamine formation at receiving and refrigerated product storage.

2. You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However your firm did not maintain any sanitation monitoring records for:

- Conditions and cleanliness of food contact surfaces, including utensils, gloves, etc.;
- Prevention of cross contamination from insanitary objects to food, food packaging material, and food contact surfaces, including utensils, gloves and outer garments, etc.;
- Maintenance of hand washing, hand sanitizing, and toilet facilities;
- Protection of food, food packaging material, and food contact surfaces from adulterants;
- Proper labeling, storage and use of toxic compounds, and;
- Control of employee health conditions that could result in the microbiological contamination of food, food packaging material, and food contact surfaces.

  These sanitation control records are required for the processing (repacking) of dried anchovies.

3. You must have product specifications that are designed to ensure that the fish and fishery products you import are not adulterated because they may be injurious to health or because they may have been processed under insanitary conditions, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have adequate product specifications for vacuum-packaged, salted mackerel and dried anchovies that you import [redacted] Your product specifications for vacuum-packaged, salted mackerel do not list *Clostridium botulinum* as a food safety hazard and your product specifications for dried anchovies do not list pathogen growth and toxin formation .

4. You must implement an affirmative step which ensures that the fish and fishery product(s) you import were processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm does not have an adequate affirmative step for vacuum-packaged, salted mackerel and dried anchovies that you import [redacted] Although you have the HACCP plan from the foreign manufacturer, you do not have a written guarantee from this foreign manufacturing assuring compliance with FDA's Seafood HACCP regulation, including a statement that they are implementing their HACCP plan as written.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your processing plant is operating in compliance with all applicable statutory requirements and regulations. It is also your responsibility to ensure not only that the current objectionable conditions are corrected, but that appropriate policies and procedures are implemented to prevent recurrence of the problems. Failure to make corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction. Your facility may also be placed on Import Alert 16-119 if you do not correct the import verification deficiencies noted during this and previous inspections.

Please note that we also found *Salmonella* species in a sample of bulk white sesame seeds taken on 8/05/04 [redacted] The presence of the harmful bacteria renders this article of food adulterated within the meaning of Section 402(a)(1) of the Act . In your written response, please describe to us how you intend to remedy the adulteration for this lot of thirty-one 50 pound bags, and what steps you have implemented to prevent its recurrence.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective actions cannot be completed within 15 working days, please state the reason for the delay and the time by which the corrections will be completed.

Please send your written reply to:

Pamela B. Schweikert, Director, Compliance Branch
U.S. Food and Drug Administration
Los Angeles District
19701 Fairchild
Irvine, CA 92612-2445

If you have questions regarding any issue in this letter, please contact Mr. Robert B. McNab, Compliance Officer at (949) 608-4409.

Sincerely,

Alonza E. Cruse
District Director